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## Romania

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### Amendments in biotech legislation

#### Report Categories:

Biotechnology

#### Approved By:

HOA VAN HUYNH

#### Prepared By:

MONICA DOBRESCU

#### Report Highlights:

The legislation concerning the deliberate release into the environment of genetically modified organisms (GMO) was recently amended by the Chamber of the Deputies, the second, but decisional chamber of the Romanian Parliament for this area. Due to the complexity of the issues, final adoption of the law has taken more than 18 months, from the moment it was introduced for debate. Main amendments refer to the composition of the Biosafety Commission and the decision process in the case of Safeguard Clause. In addition, the type of information that can be made available to public was limited to information strictly non-confidential provided by the notifier in its application.

Romania began the process of transposing the legislation on genetically modified organisms shortly before becoming an EU member in 2007. The main legal framework for bio-engineered products is represented by Emergency Ordinance 43/2007 (E.O.) transposing [Directive 2001/18](#) regarding the deliberate release into the environment of genetically modified organisms and Emergency Ordinance 44/2007 [Directive 90/219](#) referring to contained use of genetically-modified micro-organisms through (later approved through Law 3/2008).

Published in June 2007, the EO 43/2007 was debated and approved by the Senate three months later, in October 2007. Chamber of Deputies, the second chamber of the Romanian Parliament, debated the draft in May 2009 and the final version was published in the form of Law 247/2009.

### **The Regulatory Bodies**

According to E.O. 43/2007, approved through Law 247/2009 regarding the deliberate release of GMOs in the environment, the competent authorities in implementing and enforcing all activities related to the use of GMOs, and all activities concerning the deliberate release of GMOs are:

- the central public authority for environment protection - Ministry for Environment (ME), which coordinates and ensures the application of precaution principle to avoid potential adverse effects of GMOs on human health and environment as a result of obtaining, using and commercializing these organisms
- the Competent Authority (CA) which is in this case, the National Agency for Environment Protection (NAEP), whose main responsibilities are:
  - receive, administer and assess the technical content of the notification
  - consult with all responsible bodies including the Biosafety Commission
  - issue, revise, suspend or withdraw authorizations/approvals
  - ensure there is a functional national laboratory for GMOs detection and determination
  - establish and administer the electronic registry for notifications, authorizations, approvals and their status
  - establish and administer the Registry for data on GMOs import, export and transit.
- Biosafety Commission (BSC) whose major responsibilities are:
  - scientifically assess the notifications in respect to risks on human health and environment;
  - issue a scientific notice; the notices and the minutes of their meetings are not confidential and they have to be submitted to the CA, in both Romanian and English
  - request additional information to the involved parties and inform the CA about such requests
  - work with the involved parties to set up plans in case of major risks and safeguard application
- National Guard for Environment (NGE) is the control authority ensuring the right enforcement of these provisions
- the Ministry of Agriculture, Forests and Rural Development, the Veterinary and for Food Safety National Authority, and the Ministry of Public Health also have roles in implementing the provisions of this law.

### **Major amendments**

In order to closely follow the original title of the Directive 2001/18 which E.O. 43/2007 transposed, the expression “placing on the market” has been removed, leaving “deliberate release in the environment”.

In the chapter “General obligations”, it is stated that the person who submits the notification is responsible for accuracy of the information included into the notification and in all the documents submitted to the national authorities and at EU level as part of the authorization process.

The law brings changes in the composition of the Biosafety Commission, as follows:

- Three full members and one substitute nominated by the Romanian Academy and/or the institutions under its management
- Three full members and one substitute nominated by the Academy for Agricultural Sciences and Forestry and/or the institutions under its management
- Three full members and one substitute nominated by the Medical Science Academy and/or the institutions under its management

- Three full members and one substitute nominated by universities, research and development institutes with biological, agricultural, medical, environment protection and related areas.

The difference between the previous rules and the new ones is the mandatory allocation of a certain number of members to be selected from each institution mentioned-above. Following the nominations from the bodies listed above, the composition of the Biosafety Commission will be approved through an order issued by the central authority for environment protection.

The statement referring to the Safeguard Clause has been also amended in the sense that the decision regarding the initiation of the procedure on the Safeguard Clause belongs to the central public authority for environment protection based on the notices issued by the other responsible authorities mentioned above. Previously, the other authorities responsible for this topic were only consulted by the central public authority for environment protection.

Notifications regarding the deliberate release into the environment of genetically modified organisms, representing the genetically superior plants, for other purposes than placing on the market, will be submitted for consultation and approval by the CA only to the Biosafety Commission and central public authority for agriculture, not to all authorities with responsibilities for placing GMOs on the market.